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EXAMINER

COLEMAN, BRENDA LIBBY

ART UNIT

PAPER NUMBER

1624

DATE MAILED: 04/09/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/623,726

Applicant(s)

ALSTERMARK et al.

Examiner

Brenda Coleman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-37 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☒ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3, 5 & 7 20) ☐ Other:

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DETAILED ACTION

Claims 1-37 are pending in the application.

Priority

1. Any non-provisional application claiming the benefit of one or more prior filed copending nonprovisional applications or international applications designating the United States of America must contain or be amended to contain in the first sentence of the specification following the title a reference to each such prior application, identifying it by application number (consisting of the series code and serial number) or international application number and international filing date and indicating the relationship of the applications. Cross - references to other related applications may be made when appropriate.

“This application is a national stage entry under 35 U.S.C. § 371 of PCT/SE00/01254, filed June 15, 2000.” is suggested.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-37 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following reasons apply:

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- a) "Derivative" in claims 1-37 implies more than what is positively recited. See a "pharmaceutically acceptable derivative thereof".
- b) Claim 6 recites the limitation "and/or interrupted by an O atom" in the definition of R⁴. There is insufficient antecedent basis for this limitation in the claim.
- c) Claim 11 recites the limitation "which group is also optionally interrupted by an O" in the definition of A. There is insufficient antecedent basis for this limitation in the claim.
- d) A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 16 recites the broad recitation substituted by a cyano

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group, and the claim also recites preferably in the 4-position relative to B which is the narrower statement of the range/limitation.

- e) Claim 19 is a substantial duplicate of claim 18, as the only difference is a statement of intended use which is not given material weight. Note In re Tuominen 213 USPQ 89.
- f) Claims 20 and 21 are substantial duplicates of claim 1, as the only difference is a statement of intended use which is not given material weight. Note In re Tuominen 213 USPQ 89.
- g) Claims 22 and 23 provides for the use of a compound as defined in claim 1, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.
- h) Claim 24 is vague and indefinite in that it is not known what is meant by a person susceptible to. Everyone is susceptible to arrhythmia.
- i) "Derivative" in claims 26-37 implies more than what is positively recited. See a "protected derivative thereof".

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

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Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

3. Claims 22 and 23 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

4. Claim 26 is rejected under 35 U.S.C. 102(b) as being anticipated by Yamawaki et al., Chemical & Pharmaceutical Bulletin. Yamawaki teaches the compounds of the instant invention where instant R¹ is OH, R² is H, R⁷-B- is CH₃ and R⁵ and R⁶ are H. See example 17 on page 2366.

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5. Claim 26 is rejected under 35 U.S.C. 102(b) as being anticipated by Garrison et al., Journal of Medicinal Chemistry. Garrison teaches the compounds of the instant invention where instant R^1 and R^2 are H, R^7 -B- is CH_3 or cyclopropyl, R^5 is H or CH_3 and R^6 is H. See examples 15 and 30 on page 2561.

6. Claim 26 is rejected under 35 U.S.C. 102(b) as being anticipated by Schoen et al., U.S. Patent Number 5,576,327. Schoen teaches the compounds of the instant invention where instant R^1 is CH_3 , $CH_3CH_2CH_2$, $CH_3(CH_2)_3$, etc., R^2 is CH_3 , $CH_3CH_2CH_2$, $CH_3(CH_2)_3$, etc. or R^1 and R^2 together are $-(CH_2)_5-$, $-(CH_2)_4-$, etc., R^7 -B- is $CH_3CH_2CH_2$, $CH_3(CH_2)_4$, CH_3 , cyclopropyl, CH_3CH_2 , cyclohexyl, isopropyl, $CH_3(CH_2)_3$, etc., R^5 is H or CH_3 and R^6 is H. See examples 1-4 and also examples 5-33, 35-69, 71-74, etc.

7. Claim 26 is rejected under 35 U.S.C. 102(b) as being anticipated by Schoen et al., U.S. Patent Number 4,912,113. Schoen teaches the compounds of the instant invention where instant R^1 is CH_3 , $CH_3CH_2CH_2$, etc., R^2 is CH_3 , $CH_3CH_2CH_2$, etc. or R^1 and R^2 together are $-(CH_2)_5-$, $-(CH_2)_4-$, etc., R^7 -B- is $CH_3CH_2CH_2$, $CH_3(CH_2)_4$, CH_3 , cyclopropyl, cyclohexyl, isopropyl, etc., R^5 is H or CH_3 and R^6 is H. See examples 1-7, 9-21, 24-26, 30-36, 38-45, C1-C9, C11, etc.

8. Claim 26 is rejected under 35 U.S.C. 102(b) as being anticipated by Schoen et al., U.S. Patent Number 4,906,640. Schoen teaches the compounds of the instant invention where instant R^1 is H, CH_3 , $CH_3CH_2CH_2$, etc., R^2 is H, CH_3 , $CH_3CH_2CH_2$, etc. or R^1 and R^2 together are -

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(CH₂)₅-, etc., R⁷-B- is CH₃CH₂CH₂, CH₃(CH₂)₃, CH₃(CH₂)₂, CH₃, cyclohexyl, isopropyl, etc., R⁵ is H or CH₃ and R⁶ is H. See examples 1, 3-44, 46, 47, 49, 56-66, C1-C7, C9, C10, etc.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over Schoen et al., U.S. Patents 5,576,327. The generic structure of Schoen encompasses the instantly claimed compounds (see Formula II). Examples 1-74 differ only in the nature of the R¹, R² and R³ substituents. Column 3, lines 30-34 defines the substituent R¹ as an alkyl group having 1-6 carbon atoms or a cycloalkylalkyl group having 4-7 carbon atoms, R² and R³ as independently lower alkyl or together form an alkylene chain having 3-6 carbon atoms. Compounds of the instant invention are generically embraced by Schoen in view of the interchange ability of R¹, R² and R³ substituents of the bispidine ring system. Thus, one of ordinary skill in the art at the time the invention was made would have been motivated to select for example cyclobutyl as well as other possibilities from the generically disclosed alternatives of the reference and in so doing obtain the instant compounds in view of the equivalency teachings outlined above.

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10. Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over Schoen et al., U.S. Patents 4,912,113. The generic structure of Schoen encompasses the instantly claimed compounds (see Formulae II and IIa). Examples 1-45, C1-C13 differ only in the nature of the R¹, R² and R³ substituents. Column 1, lines 48-55 defines the substituent R¹ as an alkyl group having 1-6 carbon atoms or a cycloalkylalkyl group having 4-9 carbon atoms, R² and R³ as independently lower alkyl or together form an alkylene chain having 3-6 carbon atoms and column 9, lines 12-13 defines the substituent R^{1'} for formula IIa as the meaning given for R¹ with the exception of benzyl. Compounds of the instant invention are generically embraced by Schoen in view of the interchange ability of R¹, R² and R³ substituents of the bispidine ring system. Thus, one of ordinary skill in the art at the time the invention was made would have been motivated to select for example cyclobutyl as well as other possibilities from the generically disclosed alternatives of the reference and in so doing obtain the instant compounds in view of the equivalency teachings outlined above.

11. Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over Schoen et al., U.S. Patents 4,906,640. The generic structure of Schoen encompasses the instantly claimed compounds (see Formula II). Examples 1-66 and C1-C10 differ only in the nature of the R¹, R² and R³ substituents. Column 1, lines 53-58 defines the substituent R¹ as an alkyl group having 1-6 carbon atoms or a cycloalkylalkyl group having 4-7 carbon atoms, R² is hydrogen or lower alkyl and R³ as hydrogen or lower alkyl or R² and R³ together form an alkylene chain having 3-6 carbon

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atoms. Compounds of the instant invention are generically embraced by Schoen in view of the interchange ability of R¹, R² and R³ substituents of the bispidine ring system. Thus, one of ordinary skill in the art at the time the invention was made would have been motivated to select for example hydrogen or butylene as well as other possibilities from the generically disclosed alternatives of the reference and in so doing obtain the instant compounds in view of the equivalency teachings outlined above.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

12. Claim 26 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims of copending Application No. 09/623,705.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of U.S.S.N. 09/623,705 embrace the compounds of the instant invention where R⁷ is optionally substituted phenyl.

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This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brenda Coleman whose telephone number is (703) 305-1880. The examiner can normally be reached on Mondays and Tuesdays from 9:00 AM to 3:00 PM and from 5:30 PM to 7:30 PM and on Wednesday thru Friday from 9:00 AM to 6:00 PM.

The fax phone number for this Group is (703) 308-4734 for "unofficial" purposes and the actual number for **OFFICIAL** business is **308-4556**.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.



Brenda Coleman
Primary Examiner AU 1624
April 5, 2002